



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/778,388 | 02/07/2001 | Francis C. Szoka JR. | 13054.01600 | 4514 |

7590

07/24/2003

Nathan P. Koenig
Crosby, Heafey, Roach & May
P.O. Box 7936
San Francisco, CA 94120-7936

EXAMINER

SCHNIZER, RICHARD A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1635

DATE MAILED: 07/24/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/778,388

Applicant(s)

SZOKA ET AL.

Examiner

Richard Schnizer, Ph. D

Art Unit

1635

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) ____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: 6, 14 and 16-18.

Claim(s) rejected: 1, 2, 5, 7, 10-13, 15, and 19-52.

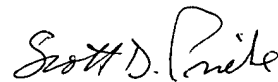
Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 2. NOTE: Amendments to claims 1-29 would require that the compositions are non-polymeric. This new limitation would necessitate further search and consideration. Amendments to claims 30-52 would require that the orthoester directly attaches to the hydrophobic portion via an oxygen atom. This new limitation would necessitate further search and consideration.

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicant correctly points out that Sparer fails to teach an encapsulator that is lipidic, liposomal, micellar, or an emulsion, therefore the obviousness rejection of claims 19, 30-33, 38, and 39 over Sparer in view of Mohr is withdrawn. These claims stand rejected under 35 USC 112, first paragraph for new matter for the reasons of record in Paper No. 9.

Continuation of 5. does NOT place the application in condition for allowance because: the amendments were not entered for the reasons set forth in (2) above. Amendment of claims 30-52 to require require that the orthoester directly attaches to the hydrophobic portion via an oxygen atom, would have overcome the new matter rejection, but necessitated new search and consideration, and was not entered. With respect to the 102 rejections over Klaveness and Harris, amendment to require non-polymeric compositions would have overcome the rejections, , but necessitated new search and consideration, and was not entered. Applicant's arguemnts that neither Klaveness nor Harris describe a species wherein ortho ester hydrolysis results in separation of a hydrophilic portion from a hydrophobic portion, but rather in the separation of two amphiphilic molecules are unpersuasive. Because amphiphilic molecules clearly contain hydrophilic and hydrophobic portions, division of a molecule into two amphiphilic poritons clearly entails separation of hydrophobic from hydrophilic portions



SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER